

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Effect of massage on physiological Parameters of Premature infants under Nasal continuous positive airway pressure through nasal (NCPAP) in Al-Zahra Hospital, Tabriz, 2010.

#### Protocol summary

##### Summary

This triple-blind study investigates the effect of massage on physiological responses of premature infants treated with Nasal-CPAP in NICU. A total of 90 premature infants who are eligible will be randomly allocated into the following three groups: control, experimental group 1 (massage with coconut oil) and experimental group 2 (sunflower oil). Massage therapy is done by the researcher (NICU student) with modify Weiss method in accordance with the conditions of newborns and neonatologist order. Then the baby will be massaged with coconut and sunflower oils during the day and every 15 minutes on three consecutive days. The massage starts from the neck and ends on the legs. Neck, back, hands, and legs are massaged but the head, chest, and abdomen are not massaged. Respiratory rate, heart rate, blood pressure, temperature, and oxygen saturation, inhaled oxygen concentration and neonatal complications will be measure five minutes before the procedure and three times during the massage (5, 10, and 15 minutes after the message) and 5 minutes after the massage and compared between groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201101234613N3**  
Registration date: **2011-03-29, 1390/01/09**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2011-03-29, 1390/01/09

##### Registrant information

##### Name

Sousan Valizadeh Dehkharghani

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

009804134751706- 34796770

##### Email address

valizades@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tabriz University of Medical Sciences

##### Expected recruitment start date

2011-02-14, 1389/11/25

##### Expected recruitment end date

2011-05-22, 1390/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of massage on physiological Parameters of Premature infants under Nasal continuous positive airway pressure through nasal (NCPAP) in Al-Zahra Hospital, Tabriz, 2010.

##### Public title

Effect of massage on physiological Parameters of Premature infants

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: gestational age 28-32 weeks and

weight 1000 to 2000 grams, treated with continuous positive airway pressure, not treated by respirator, infants under NCPAP after 12 hours of birth, Axillary temperature is between 36/5-37° C, not having abnormalities or congenital neurological problems, cardiac-vascular and inherited diseases, Arterial blood oxygen saturation at least 92 percent, not having contraindication for touch. Exclusion criteria: mother's addiction to alcohol, cigarettes or drugs or other medications, any indication for surgery, gastric disorders, intestinal or central nervous system disorders, having a chest tube, infants who require FIO2 more than 70 percent, having serious systemic infection, tachycardia (more than 180 beats per minute), bradycardia (less than 90 beats per minute), resistant (more than two time)

**Age**

From **28 years** old to **32 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Triple blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Deputy of Research, Tabriz University of Medical Sciences

**Street address**

Deputy of Research, Tabriz University of Medical Sciences

**City**

Tabriz

**Postal code**

51668-44199

**Approval date**

2011-01-17, 1389/10/27

**Ethics committee reference number**

89/10/27 در هشتاد و هشتمین جلسه کمیته اخلاق مورخ

**Health conditions studied****1****Description of health condition studied**

Premature Newborn NCPAP hospitalized in NICU

**ICD-10 code**

P22.0

**ICD-10 code description**

Respiratory distress syndrome of newborn

**Primary outcomes****1****Description**

physiological Parameters of Premature infants under NCPAP

**Timepoint**

5 minutes before massage, 5, 10, 15 minutes massage and 5 minutes after massage

**Method of measurement**

monitor device model S1600 poyandegan rahe saadat, wellshaleene digital and manufactured Medin Easy Blender

**Secondary outcomes**

empty

**Intervention groups****1****Description**

In premature infants treated with NCPAP initially Respiratory Rate (RR), heart rate (HR), Fraction of Inspired oxygen (FIO2) and arterial oxygen saturation (SatO2), blood pressure (BP) and body temperature (from axillary) (T) in position Peron determined and is recorded in the checklist. The infants were randomly assigned to three groups: Intervention groups 1(massage with sunflower oil) 10 ml oil per kg birth weight is used. Massage therapy is done by the researcher (NICU student) with modify Weiss method in accordance with the conditions of newborns and neonatologist order. Then the baby's massage with coconut and sunflower oils during the day and once every 15 minutes on three consecutive days is given. Infant massage started of the neck and ends his legs. Neck, back and hands and legs infant massage is given and the head, chest and abdominal massage does not hold the baby. Research fellow in five minutes before the procedure and three times during the massage (5 minutes, 10 and 15) and then after 5 minutes of massage, respiration, heart rate, blood pressure and temperature, and oxygen saturation concentration inhaled oxygen and neonatal complications resulting from the above NCPAP.

**Category**

Treatment - Drugs

## 2

### Description

Intervention group 2 (massage with coconut oil) 10 ml oil per kg birth weight is used. Massage therapy is done by the researcher (NICU student) with modify Weiss method in accordance with the conditions of newborns and neonatologist order. Then the baby's massage with coconut and sunflower oils during the day and once every 15 minutes on three consecutive days is given. Infant massage started of the neck and ends his legs. Neck, back and hands and legs infant massage is given and the head, chest and abdominal massage does not hold the baby. Research fellow in five minutes before the procedure and three times during the massage (5 minutes, 10 and 15) and then after 5 minutes of massage, respiration rate, heart rate, blood pressure and temperature, and oxygen saturation concentration and neonatal complications resulting from the above NCPAP.

### Category

Treatment - Drugs

## 3

### Description

Control group (routine care without massage) also were measured respiration rate, heart rate, blood pressure and temperature, and oxygen saturation concentration in the same time.

### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Alzahra hospital

##### Full name of responsible person

Najmeh Ajoodaniyan

##### Street address

Al-Zahra Hospital, Artesh Hospital, Baghshmal Crossroads, Tabriz

##### City

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Research Deputy, Tabriz University of Medical Sciences

##### Full name of responsible person

Dr Sousan Valizadeh

##### Street address

Pediatric Department of Nursing and Midwifery Faculty

##### City

Tabriz

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Research Deputy, Tabriz University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

empty

#### Domestic or foreign origin

empty

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

empty

## Person responsible for general inquiries

### Contact

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tabriz University of Medical Sciences

#### Full name of responsible person

Najmeh Ajoodaniyan

#### Position

Nursing Master of Science Student neonatal intensive care

#### Other areas of specialty/work

#### Street address

Nursing And Midwifery Faculty

#### City

Tabriz

#### Postal code

#### Phone

+98 41 1479 0365

#### Fax

+98 41 1479 6969

#### Email

ajoodaniyan@yahoo.com ajoodaniyan.n@gmail.com

#### Web page address

## Person responsible for updating data

### Contact

## Sharing plan

#### Deidentified Individual Participant Data Set (IPD)

empty

#### Study Protocol

empty

#### Statistical Analysis Plan

empty

#### Informed Consent Form

empty

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*